MEDICATION FORMULARY

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- This document replaces the Medicine – Evaluation of Medicines for Use in Public Hospitals Policy
- This document is to inform relevant SCHN staff on:
  - Formulary Definitions
  - Mandatory policy statements
  - Process for the approval of medicines and their use for listing on the SCHN formulary, or for individual patient use
  - This document should be read in conjunction with NSW Health PD2016_033 – Approval Process of Medicines for Use in NSW Public Hospitals
- The relevant application forms are accessible as below.
  - SCHN Individual Patient Usage (IPU) Form
  - Individual Patient Use (IPU) Renewal and Report Form
  - SCHN Formulary Application Form

CHANGE SUMMARY

- N/A New Document
- 18/3/20: Minor review - title change and formatting.

READ ACKNOWLEDGEMENT

- All relevant SCHN staff should be aware of the Policy.

This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st April 2020	**Review Period**: 3 years
Team Leader:	Pharmacist	**Area/Dept**: Clinical Governance Unit

1 Formulary Definitions:

1.1 Formulary:

All public hospitals in NSW must have a formally constituted, multidisciplinary Drug and Therapeutics Committee (DTC)/Medicines and Therapeutics Committee (MTC) in place and a hospital formulary.

A hospital formulary is a hospital specific list of medicines and related information approved by the MTC. It includes, but is not limited to, medicines and medicine-associated products or devices, medication charts, medication use policies, important ancillary drug information, decision-support tools, and facility guidelines.

Prescribers working within public hospitals in NSW may only prescribe medicines included in the relevant hospital formulary and in accordance with this policy.

1.2 Formulary Medication:

Medications on the formulary include those that are listed by CHW & SCH respectively to be utilised by prescribers for eligible inpatients and outpatients. The formulary excludes medicines for research purposes or clinical trials. Approval for use of these medicines within SCHN should be referred to the relevant Human Research Ethics Committee. Additionally, medicines provided as supportive care as part of a clinical trial protocol require review on an individual trial basis by the clinical trials team.

If a SCHN prescriber requests a medication to be added to the SCHN Formulary due to increased individual usage, the availability of a new paediatric specific formulation and/or a new medication, a SCHN Formulary Application Form. The SCHN MTC may request Network Guidelines/Protocols or training & education packages from the application team with the administration of a medication on the Formulary as required.

To check if a medication is currently available on the SCHN formulary, please contact your local pharmacy department for assistance:

- Children's Hospital Westmead: (02) 9845 2700
- Sydney Children's Hospital: (02) 9382 1386

1.3 Non-Formulary Medication:

Any medication that is not readily available for patient use on the hospital formulary. This medication can only be accessed on an individual patient basis outside the hospital formulary regulations. It involves completion of an Individual Patient Use (IPU) application form by the treating team that is evaluated by the SCHN MTC or site-based Committee depending on the cost.

1.4 Patient Consent:

Patient and/or parent consent is required for all medication utilised for individual patient use in a non-formulary, off-label capacity and/or as part of medication & compassionate access programs. This should include a verbal consent discussing the medication, its use, possible adverse effects and monitoring required as well as a written consent form for the patients record.

1.5 Off-label Medication Use:

This involves the use of a registered medication that is not included in the TGA approved product information or which is disclaimed in the product information. Lack of TGA approval of a medicine does not imply that a drug is ineffective, contraindicated or disapproved. In the paediatric setting, off-label use of medicines is prevalent and may offer the only treatment option. Prescribing medicines off-label requires an understanding and consent agreement between the patient and the prescriber as to how the medicine will be utilised and continue to be obtained.

2 Processes:

2.1 Submission – Formulary

SCHN senior clinician(s) or teams requesting the hospital formulary addition must complete the SCHN Formulary Application form for review and approval by the SCHN MTC. Each site should liaise with their counterpart at the relevant site for review of medication prior to a Formulary application submission. The formulary submission process is demonstrated in Appendix One.

The formulary submission should include the objective of formulary addition or indication update. Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapies and common and serious adverse effects should be submitted with the application. All applications must be fully completed and typed – it should be noted that any incomplete applications will be returned to the applicant for completion prior to consideration by the SCHN MTC.

The consideration process for evaluation of a formulary application by the SCHN MTC is as per Appendix Two – NSW Therapeutic Advisory Group (NSW TAG) – Decision Algorithm for evaluation of medicines for formulary listing in public hospitals. This demonstrates best practice for how a medication should be evaluated for formulary listing.

2.2 Application – Individual Patient Use (IPU)

IPU approval of specific medicines is required when a therapeutic need exists for a medicine which would not otherwise be available on the hospital formulary, including medicines used in an off-label manner, or the use of unregistered medicines. This includes medications funded by SCHN or those obtained via compassionate access and medicine access programs. As described below, this process should assist with the assessment on whether such use is justified and subsequently whether an application should be made to the MTC.

SCHN senior clinician(s) requesting use of a medicine for IPU should complete the SCHN IPU Application Form.

Where appropriate, a written clinical protocol that includes, as a minimum, indications and circumstances of use, safe prescribing and administration details, contraindications, precautions and interactions with other therapy and common and serious adverse effects should be submitted with the application. All applications must be fully completed and typed – it should be noted that any incomplete applications will be returned to the applicant for completion prior to consideration by the relevant Committee.

If the cost of the medication or treatment cost is greater than $10 000 annually, the application is referred to the SCHN MTC for review, see Appendix Three for the process. Consideration and review of applications will occur at the next relevant SCHN MTC meeting for all applications received up to 2 weeks prior to the scheduled meetings. The meetings are generally scheduled for the first Monday of the month (February – December each year).

Streamline IPU applications are available for a small subset of medications that may be restricted to patients who meet certain criteria, however, use is considered standard of care with acceptable evidence in paediatrics. Please contact your local pharmacy department for further information.

The consideration process for evaluation of an IPU application by the MTC is as per Appendix Four – NSW Therapeutic Advisory Group – Decision Algorithm for evaluation of medicines for Individual Patient use (IPU) approval. This demonstrates the best practice for how a medication should be evaluated for IPU approval.

2.3 Management – Urgent Applications & Outcomes

2.3.1 Urgent Applications

In circumstances where use of a specific medicine is required urgently to prevent or minimise harm to a patient, the IPU application process must still be followed. The rapid assessment of the IPU application will be facilitated by the local site Committee Chair or the Network MTC secretary.

At SCHN, in extenuating circumstances, urgent IPU applications are escalated for out of session approval via the Chairs of the local CHW & SCH Committee as well as the secretary of the Network MTC and are discussed and ratified at the following MTC meeting, either local or Network, depending on cost.

2.3.2 Outcomes

Applicants will be informed of the outcome of IPU and Formulary applications, together with details and or restrictions of the approval, monitoring and reporting requirements. The applicant will also be notified of any staff education and/or training or specific patient education requirements with the approval.

2.4 Monitoring – Reporting & Renewal

All approvals will have a review date set at the time of approval at the relevant MTC meeting.

During this period of time, clinicians will be responsible for outcome reporting to the local site Committee or Network MTC by utilising the SCHN IPU Renewal & Report Form.

Any relevant requirements for review, evaluation and appropriate action associated with the use of the formulary/IPU item or guideline in addition to any adverse events must be reported.

Furthermore, these adverse events must be reported via the usual channels, including the Safety at Kids incident management system and the TGA's Adverse Events Reporting System.

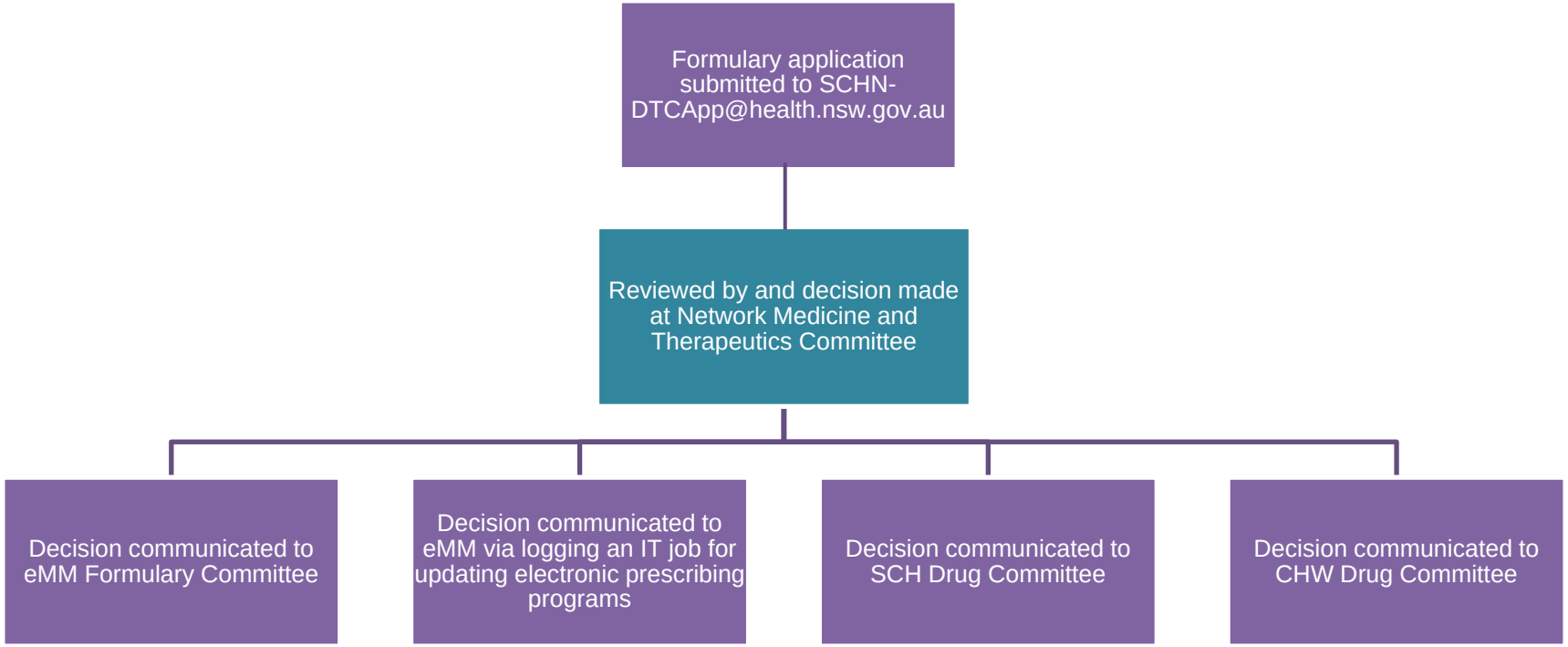
Compliance with formulary approval, resource utilisation and outcomes of treatment may be subject to a Drug Use Evaluation (DUE) process.

Continued or further IPU approvals are conditional upon completion and submission of the SCHN IPU Renewal & Report Form to the relevant committee. These forms are reviewed in the same process as IPU applications.

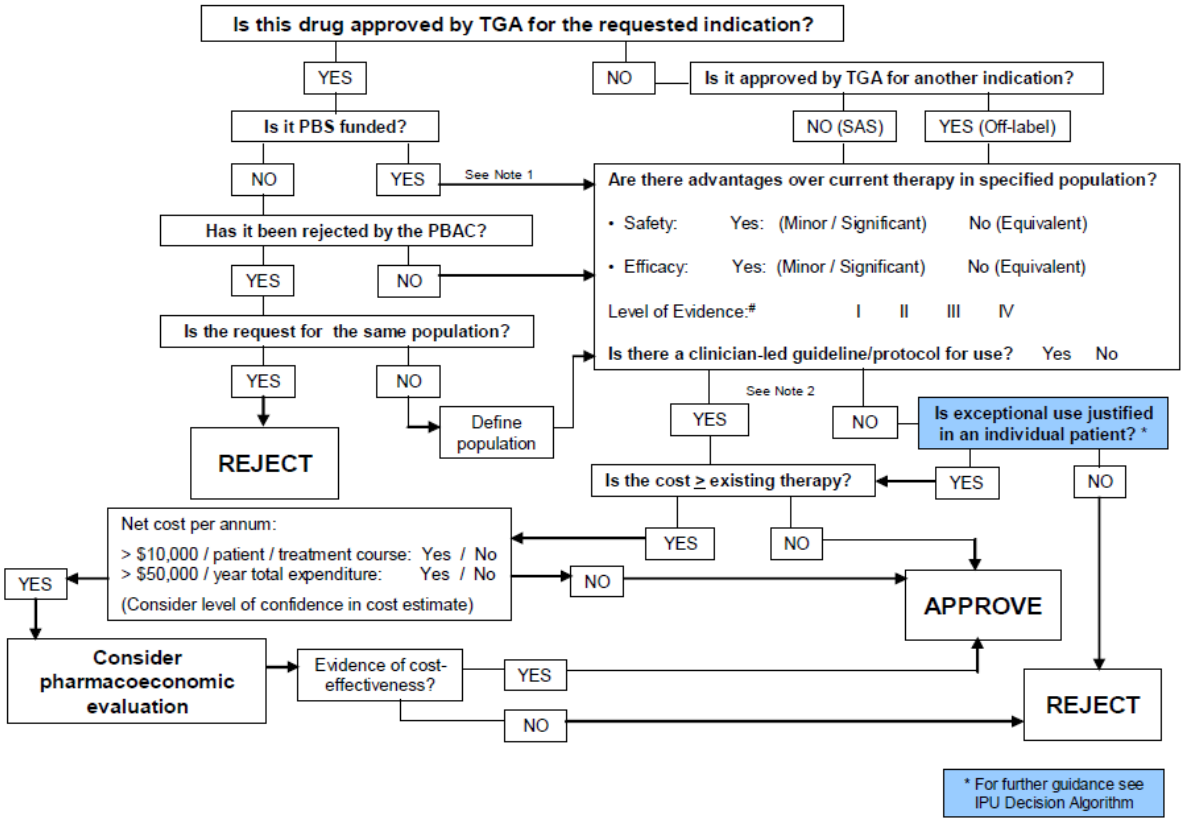
Lastly, in order to facilitate communication of MTC decisions to other NSW Local Health Districts/hospitals, the NSW TAG maintains a register of MTC decisions for NSW public hospitals. SCHN participates in this communication by periodically providing NSW TAG the decisions made by the Network MTC. The register is only accessible in the members' section of the NSW TAG website to authorised personnel including MTC members.

3 Appendices

3.1 Appendix One: SCHN Formulary Application Process



3.2 Appendix Two: NSW Therapeutic Advisory Group – Decision Algorithm for *evaluation of medicines for formulary listing in public hospitals*



Note 1:
Where a PBAC evaluation has been undertaken, the DTC may choose to accept the PBAC decision without further evaluation

Note 2:
Adequacy of evidence for comparative safety and efficacy should be assessed by the DTC in light of the clinical circumstances.* The need for a defined guideline/protocol for use should be determined on a case by case basis.

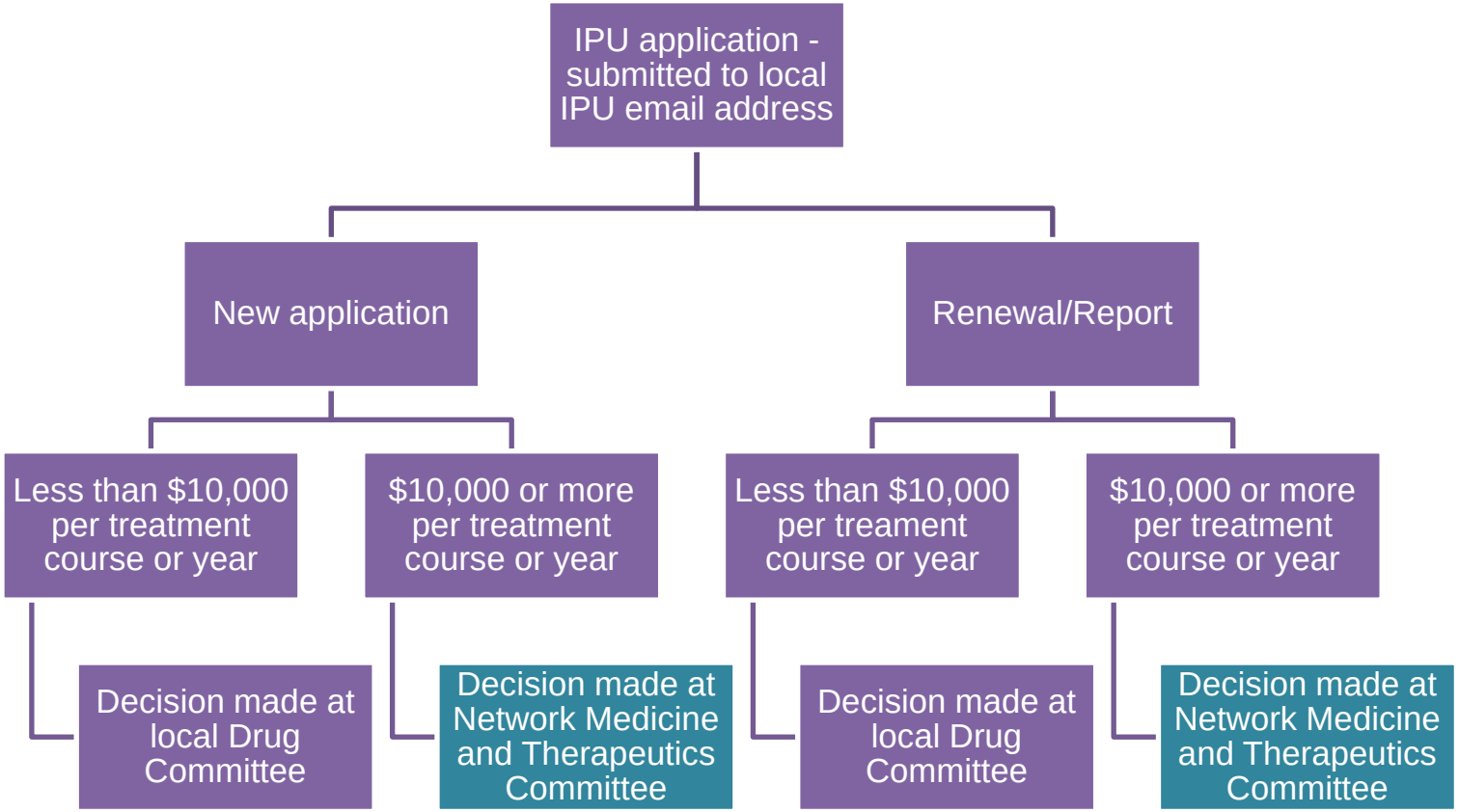
* **Evaluation of evidence**
For more detailed guidance on evaluation of evidence, see Gazarian et al. MJA 2006;185: 544-548. In particular, refer page 545: Assessing appropriateness – evaluation of evidence

 # Level of Evidence

Level I	Evidence from one or more systematic reviews of randomised controlled trials
Level II	Evidence from one or more well-designed, randomised controlled trials
Level III	Evidence from well-designed, non-randomised controlled trials; cohort, case control or interrupted time series studies
Level IV	Case series with either post-test or pre-test/post-test outcomes

(From NHMRC interim levels of evidence 2005 :www.nhmrc.gov.au/publications/_files/levels_grades05.pdf)

3.3 Appendix Three: SCHN Individual Patient Use (IPU) Application Process



3.4 Appendix Four: NSW Therapeutic Advisory Group – Decision Algorithm for *evaluation of medicines for individual patient use (IPU) approval*